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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,680	08/22/2001	Robert J. Levy	047172-0174	7085

7590

12/02/2002

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EXAMINER

SAUCIER, SANDRA E

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 12/02/2002

3

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/933,680

Applicant(s)
Levy et al.

Examiner
Sandra Saucier

Art Unit
1651



– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1 6) ☐ Other: _____

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DETAILED ACTION

Claims 1-14 are pending and are considered on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent.

Claims 1-4, 7, 9, 12, 14 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by US 5,891,196 [A].

The claims are directed to a method of treating tissue comprising: stabilizing glycosaminoglycans and cross-linking proteins on the tissue.

Glycosaminoglycans can be stabilized by using a water-soluble carbodiimide. Proteins may be cross-linked by using an aldehyde or carbodiimide.

The references are relied upon as explained below.

US 5,891,196 discloses a method of treating tissue for implantation comprising treating the tissue with a crosslinking agent such as a) glutaraldehyde or dialdehyde, treating the tissue with a carboxyl activating compound such as b) carbodiimide (EDAC or DCC or EAC), contacting the tissue with a c) heparin, which is a glycosaminoglycan, see Description of Preferred Embodiments. Please note that the treatment with EDAC would also stabilize endogenous glycosaminoglycans.

Claims 1-4, 7, 9-12 and 14 are rejected under 35 U.S.C. 102(b) as being

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clearly anticipated by US 4378224 [B].

The claims have been discussed above.

US 4,378,224 discloses a method of treating tissue comprising treating the tissue with (5) EDAC about pH 5 (10) treating the tissue with an aliphatic diamine such as hexanediamine, (17) treating the tissue with glutaraldehyde (col. 6). Practice of the method disclosed by '224 is considered to produce a tissue with the same characteristics as claimed because the steps as disclosed and as claimed are essentially the same. Practice of the same method is reasonably expected to produce the same product with the same characteristics in the absence of evidence to the contrary.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,891,196 [A].

The claims were discussed above.

US 5,891,196 states in col. 4, l. 50, that the method may be used for cardiac valve tissue and does not limit the disclosure to any specific animal. Therefore the use of this method to prepare bovine or porcine tissue is considered to be obvious in the absence of evidence to the contrary.

Claims 5, 6 and 13 are rejected under 35 U.S.C. 103(a) as being

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unpatentable over US 4,378,224 [B] in view of US 5,447,536 [A3].

US 4,378,224 states in col. 2, l. 45, that the method may be used for heart valve tissue and does not limit the disclosure to any specific animal. Therefore the use of this method to prepare bovine or porcine tissue is considered to be obvious in the absence of evidence to the contrary.

US 5,447,536 is relied upon to disclose that the pH of a cross-linking reaction can vary and is preferred from about 6.5–7.4 (col. 5, l. 60).

US '224 also states in col. 3, l. 52 that the pH of the carbodiimide solution should be kept about 4.7 to about 5.2. As the claims use the modifier “about” pH 6.9 to 7.9 without any definition of the term about, the pH range of the reference and the pH range of the claim are considered to overlap. Further, adjustment of pH is well within the purview of one of skill in the art in the absence of criticality, particularly when the disclosure of US 5,447,536 is taken.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,378,224 [B] in view of US 6,214,054 [C] or US 5,865,849 [D].

Claim 8 is directed to the use of a second carbodiimide to cross-link proteins on the tissue.

US 4,378,224 discloses a method of treating tissue comprising treating the tissue with (5) EDAC about pH 5, (17) treating the tissue with glutaraldehyde (col. 6).

The reference lacks the use of a second carbodiimide for cross-linking protein.

US 6,214,054 discloses the equivalence of the class of carbodiimides with glutaraldehyde for the cross-linking of proteins in implants (col. 4, l. 36–43).

US 5,865,849 discloses the equivalence of the class of carbodiimides with glutaraldehyde for the cross-linking of proteins in implants (col. 4, l. 65 onwards).

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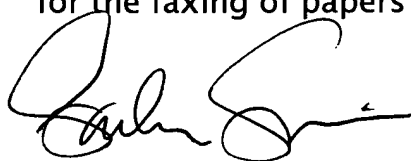
The substitution of a second carbodiimide for the glutaraldehyde in the process of '224 would have been obvious because either '054 or '849 discloses the equivalency of these compounds for use in fixing or crosslinking proteins in tissue useful for implantation.

Please note that the claims are open to insertion of further steps.

One of skill in the art would have been motivated at the time of invention to make this substitution in order to obtain the resulting compositions suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197. The number of the Fax Center for the faxing of papers is (703) 308-2742 or (703) 305-3592.



Sandra Saucier
Primary Examiner
Art Unit 1651
November 29, 2002